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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,386	SHELBY, JANE	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *6,8,9 and 13-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,10-12 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-16 and 25-29) and "non-corneal" cells as an elected species in the reply filed on 6/24/2010 is acknowledged. The traversal is on the ground(s) that there is no burden to examine all Groups I-III. This is not found persuasive.

Applicant alleges that there would be no burden on the examiner in examining all of the claims at once, relying on M.P.E.P. §802.02. Chapter 800, however, is limited to a discussion of the subject of restriction and double patenting under Title 35 of the United States Code and Title 37 of the Code of Federal Regulations as it relates to national applications filed under 35 U.S.C. 111(a). The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority, and in applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in M.P.E.P. §1850 and is dictated by PCT Rules 13.1 and 13.2. See M.P.E.P. §801. Burden is not a consideration in a finding of lack of inventive unity; rather, according to M.P.E.P. §1850, the only consideration is whether the inventions share a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6, 8, 9, 13-16 and 17-24 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-5, 7, 10-12 and 25-29 have been considered on the merits.

Claim Objections

Claim 10 is objected to because of the following informalities: Claim 10 discloses the limitation directed to the cells being in the absence of non-cell penetrating cryoprotectant. It appears more appropriate that the "composition", instead of "cells" is in the absence of a non-cell penetrating cryoprotectant. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 11, 12 and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of "cultured and preserved" of claim 5 does not clearly point out whether the cells in the composition comprising GAG are subsequently cultured and preserved, or the previously cultured and preserved cells are in the composition. Clarification is required. For examination purpose, the limitation is considered as a subsequent process step of culturing and preserving the cells in the composition.

The limitation directed to the cells being preserved at a temperature above or below freezing disclosed in claims 11 and 12 does not clearly point out whether this step of preserving at the disclosed temperature being carried out with the cells in the composition, or the composition comprises the cells previously preserved under the disclosed condition. Clarification is required.

Claims 25-29 disclose the phrase "a storage solution comprising hyaluronan in the absence of serum and cells." It is not clear whether this limitation intends to claim that the solution in the absence of cells, or the solution comprises hyaluronan and cells, but no serum. Since the dependent claims 26-29 are directed to the cells, it appears that the cells are in the solution. However, the limitation of claim 25 is not clear whether or not the cells are a part of the storage solution. For examination purpose, the limitation is interpreted such that the kit comprises hyaluronan and cells, and does not include serum.

The limitation of claim 26 directed to the cells being stored at a temperature above 0°C does not clearly point out whether the cells are stored at the temperature as a part of the kit, or the cells in the solution being stored at the claimed temperature as the use of the storage solution. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7, 10-12, 25, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Guienne et al. (1999; Theriogenology; of record).

The claimed composition is interpreted as to comprise hyaluronic acid (HA; hyaluronan) and a cell, a tissue or an organ, without a serum.

Guienne et al. teach the composition of cells (i.e. blastocysts) in the serum-free medium comprising HA (see entire document).

With regard to the limitation directed to the intended use of the composition being for preserving cells (claim 3), this limitation does not provide any weight to the claimed composition since it does not provide any structural limitation.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "for preserving cells" does not affect the patentability of the claimed composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

The limitation of claims 5, 11, 12 and 26 is considered as the cells being cultured and preserved at above freezing temperature in the composition comprising HA. This limitation is directed to the intended use and a process of using the claimed composition, and thus, this limitation does not provide any structure to be considered for the claimed composition.

With regard to the limitation of claim 10, the composition of Quienne et al. does not contain any cryoprotectant and thus, it is considered not to contain a non-cell penetrating cryoprotectant.

Thus, the reference anticipates the claimed subject matter.

Claims 1-5, 7, 10-12, 25, 26, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Alkemade et al. (US PAT. 5,102,783; IDS ref.).

Alkemade et al. teach a composition for culturing and freezing cells (thus, preserving cells) without serum substituted by hyaluronic acid (HA; hyaluronan), thus meet the limitation of the composition comprising a cell and glucosaminoglycan or hyaluronan in the absence of serum (abstract).

According to Example 1 of Alkemade et al., embryo is stored in the composition right after isolation from the mouse morulae for freezing, and thus, the embryo is considered non-cultured (claim 4).

Alkemade et al. teach that the composition is suitable for cells or tissue such as embryos, ova and sperms (abstract), which are non-corneal (claim 7).

The limitation of claims 5, 11, 12 and 26 is considered as the cells being cultured and preserved at above freezing temperature in the composition comprising HA. This limitation is directed to the intended use and a process of using the claimed composition, and thus, this limitation does not provide any structure to be considered for the claimed composition.

With regard to the limitation of claim 10, the composition of Alkemade et al. comprises 10% glycerol (see col. 6, Table), which is well known in the art as penetrating cryoprotectant, and thus, the composition of Alkemade et al. is considered be in the absence of a non-cell penetrating cryoprotectant.

Thus, the reference anticipates the claimed subject matter.

Claims 1-3, 5, 10-12 and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindstrom et al. (EP 0516901 A1).

Lindstrom et al. teach a serum-free composition (storage solution) for enhancing preservation of eye tissue comprising HA (abstract; col. 7-8).

The limitation of claims 5, 11, 12 and 26 is considered as the cells being cultured and preserved at above freezing temperature in the composition comprising HA. This limitation is directed to the intended use and a process step of using the claimed composition, and thus, this limitation does not provide any structure to be considered for the claimed composition.

With regard to the limitation of claim 10, the composition of Lindstrom et al. does not contain any cryoprotectant because the composition is not intended for cryopreservation, and thus, it is considered not to contain a non-cell penetrating cryoprotectant.

Since the composition of Lindstrom et al. is for highly metabolic epithelial cell layer (col. 8, Example 1), it is considered that the cells of Lindstrom et al. are in sheets.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 10-12 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkemade et al. (supra).

Alkemade et al. teach the limitations of claims 1-5, 7, 10-12, 25, 26, 28 and 29, and thus render the claims obvious (see above).

Alkemade et al. do not particularly teach the cells being in sheets (claim 27).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to utilize any type of cell including those in sheets (e.g. epithelial layers) for the preservation purpose in the composition comprising HA in the absence of serum as taught by Alkemade et al. This is because the composition of Alkemade et al. is suitable for tissue and tissue can be layers of cells including epithelial sheets.

With regard to the limitation of claims 5, 11, 12 and 26, even if the cells are considered "cultured" cells prior to being in the composition, rather than being cultured in the composition as an intended use of the composition, it would have been obvious for the person of ordinary skill in the art at the time the invention was made to use "cultured" cells in the storage composition comprising HA for culturing and freezing the cells. Whether or not using the culture or non-cultured cells in the composition comprising HA is a matter of known choices in the art, and it does not provide any patentable weight to the claimed invention. Furthermore, whether or not cells being cultured or non-cultured, it does not provide any structural limitation to the cells.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651